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Application No.: 09/811,538 Docket No.: 22001-00005-US

REMARKS

Claims 1-46 are in the application. Claims 1-19 are directed to the elected invention. Claims 20-46 are directed to non-elected inventions and may be canceled by the Examiner upon the allowance of the claims directed to the elected invention.

The rejections of claims 1-19 under 35 U.S.C. §112, second paragraph are not deemed tenable. The term "polydiacetylene backbone" is readily understandable by those skilled in the art. The tem "polymer backbone" is widely used. For a search of literature articles on the Web of Science, turned up about 1643 hits (the Web of Science searches scientific journals that have been electronically archived wherein a hit occurs if the exact term or phrase appears in either the title, abstract or key words). For instance, see Cowie, Polymers: Chemistry and Physics of Modern Materials, Blackie Academic & Professional, 1991, Chapter 16, Polymer Liquid Crystals, p 363-368, (copy enclosed). At page 363, section 16.2 paragraph 1 states "---(ii) attachment through one terminal unit to a polymer backbone to produce a side chain comb-branch structure---." Also see page 368, Fig. 16.1. In addition, U.S. Patent No. 6,022,748 to Charych, relied upon by the Examiner, even refers to "polymer backbone" (see column 12, lines 17-26). Also, the present specification makes clear what is meant by "polydiacetylene backbone", consistent with the art (see page 1, lines 14-16 and Figure 1). The Reichert et al paper, also relied upon by the examiner, uses the term "polyacetylene backbone" (p829, paragraph 2 and p830, 1st full paragraph). On page 829, paragraph 2 states in part," ---optical properties of polydiacetylenes. The conjugated backbone of alternating double and triple bonds.---"

Concerning claim 9, persons skilled in the art aware of the present disclosure would readily appreciate that the polydiacetylene of claim 9 further defines the polydiacetylene of claim 1. Moreover, it is apparent that it is the polydiacetylene prior to being subjected to the analyte that is in non-fluorescent form.

Concerning lack of antecedent basis for "polydiacetylene", this term is explicitly recited in claim 1. The term "non-fluorescent form" has proper antecedent basis in claim 1 since it more specifically defines the form of the polydiacetylene being employed and is therefore a species within the scope of the more generic claim 1.

Claims 1-2 and 9-13 were rejected under 35 U.S.C. §102(b) as being anticipated by Reichert et al. (J. Am. Chem. Soc., 1995, 117; 829-830). Reichert et al. do not anticipate the above claims listed, among other things, Reichert et al. does not even remotely suggest detecting a change in fluorescence as required by the present invention. The technique of Reichert et al. relies upon a change in color, not a measurement of a change in fluorescence. Also the comment in the office action concerning Reichert et al that "the solution changes to a pink or orange color (the polydiacetylene of the array in the non-fluorescent form)" is not correct. Reichert et al. do not refer to the pink or orange color as being the non-fluorescent form. In fact, a pink or orange colored polydiacetylene is generally a fluorescent form of the polydiacetylene.

Reichert et al. fail to anticipate the present invention. In particular, anticipation requires the disclosure, in a prior art reference, of each and every recitation as set forth in the claims. *See Titanium Metals Corp. v. Banner*, 227 USPQ 773 (Fed. Cir. 1985), *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986), and *Akzo N.V. v. U.S. International Trade Commissioner*, 1 USPQ2d 1241 (Fed. Cir. 1986).

There must be no difference between the claimed invention and reference disclosure for an anticipation rejection under 35 U.S.C. 102. *See Scripps Clinic and Research Foundation v. Genetech, Inc.*, 18 USPQ2d 1001 (CAFC 1991) and *Studiengesellschaft Kohle GmbH v. Dart Industries*, 220 USPQ 841 (CAFC 1984).

Claims 1-19 were rejected under 35 USC 103 (a) as being unpatentable over U.S. 5,415,999 Saul, et al., in view of US patent 6,180,135 B1 to Charych et al. These cited references do not render obvious the present invention. In particular, the claims under consideration relate to detecting an analyte in a sample by contacting the sample to be tested with a three-dimensio nal array that comprises a polydiacetylene backbone and a substrate wherein the substrate has direct affinity for an analyte or is capable of binding to an analyte or is capable of reacting with an analyte. An analyte when present causes a change in fluorescence of the polydiacetylene backbone. The change in fluorescence is then detected to thereby indicate the presence of an analyte.

As discussed in the specification measuring the change in fluorescence of the array is a significantly more sensitive test than monitoring by color change. The increase in sensitivity is crucial for providing detection systems to have actual practical utility as a sensor for many applications where monitoring color change would not be satisfactory.

Moreover, as discussed in the specification, the assay method of the present invention makes possible a continuous monitoring of the binding or the interaction of an analyte. Also, since no wash steps are required in the technique of the present invention, the method is relatively simple and inexpensive to carry out.

U.S. patent 5,415,999 to Saul et al, fails to suggest or render obvious the present invention since, among other things, as recognized by the Examiner, Saul et al., fails to suggest or disclose a three-dimensional array of a polydiacetylene backbone or, according to preferred aspects of the present invention, an array that is in the form of the liposomes or tubules (see claims 2, 11 and 13). Furthermore, Saul et al., fails to suggest the present invention since Saul et al is not concerned with a change in fluorescence of a polydiacetylene backbone. Instead, Saul et al., requires a red, fluorescent, polydiacetylene film and a separate fluorescence modulation reagent. This fluorescence-modulating reagent required by Saul et al., modulates the measured emission of the film, e.g., by absorbing the emitted light, in proportion to the analyte bound, either by binding to the analyte after it has been bound or by competing with the analyte for binding sites. The fluorescence modulation reagent contains a component (e.g., an enzyme) that will reduce the fluorescence, e.g., by releasing a dye to obscure the fluorescence. In other words, the fluorescent state of the film does not change during the assay directly from binding of the analyte; rather, the emission is obscured or revealed by the action of the fluorescence modulation agent required by Saul et al. Saul et al. does not suggest measuring the change in fluorescence that is due to the interaction or binding of an analyte and the polydiacetylene. Nothing whatsoever in Saul et al suggests that the fluorescence of the polydiacetylene would or could be modulated upon analyte binding without the fluorescence modulation layer.

Charych, et al., fails to overcome the above-discussed efficiencies of Saul, et al., with respect to rendering obvious the present invention. In particular Charych, et al., does not relate to using fluorescence but instead relates to a method that monitors color change of a three-dimensional array of a polydiacetylene backbone. Nothing whatsoever in Charych et al., would suggest that the three-dimensional array could be used in a method that detects the change in fluorescence. Furthermore, the three-dimensional arrays suggested by Charych et al., are prepared in the blue form, which is the non-fluorescent form, in order to be suitable for the assays suggested therein. Charych.et al suggest a colorimetric change of polydiacetylene liposomes from blue to red in response to the analyte binding or reacting with a substrate incorporated in the liposomes. Since the technique suggested by Saul et al., requires starting with a red fluorescent film it would be counterintuitive to employ the non-fluorescent three-dimensional array suggested by Charych et al., in the method of Saul et al. Accordingly, the prior art lacks any motivation to substitute the polydiacetylene three-dimensional arrays employed by Charych et al., in the method of Saul et al. In fact, if anything, the cited art actually leads from the present invention.

Furthermore, even if such were substituted in the method of Saul et al., the present invention would still not be suggested since, as discussed above, Saul et al., require a fluorescent modulating reagent which obscures or reveals the fluorescence of emissions of the film.

In addition, the Examiner's statement that criticality has not been demonstrated for the use of fluorescent rather than colorimetric polydiacetylene backbones is not germane to this matter, since the Examiner has not even established a *prima facia* case of obviousness. When the proposed modification would change the principle of operation of the prior art being modified, as is the case here, then the teachings of the references are not sufficient to render the claims prima facie obvious. See *In re Ratti* 123 USPQ 349 (CCPA 1959). Furthermore, as discussed in the specification, fluorescence and colorimetric techniques are not the same and fluorescence clearly provides a more sensitive technique. Additionally, the slope of change for the fluorescence measurements is significantly different from that for colorimetric

measurements as clearly illustrated in Fig. 3 in this application, which further supports the non-obvious results achieved by the present invention.

Moreover, knowing that the polydiacetylene that Saul et al suggest is fluorescent does not imply that one form of polydiacetylene that Charych suggests would be non-fluorescent while the other form would be fluorescent. There is nothing in either Charych or Saul that would point to **blue** polydiacetylene having different fluorescence characteristics than **red**, or that any change in fluorescence would be of sufficient magnitude for the purpose of detecting analytes. Also, one should keep in mind that conjugated polymers are not necessarily fluorescent. For instance, see McQuade et al. Conjugated Polymer-Based Chemical Sensors, Chem. Rev., 2000, 100, No. 7, pages 2537-2574, June 2000 (copy attached) and particularly page 2538, second complete paragraph.

In addition, Claim 9 which is directed to that aspect of the present invention wherein the polydiacetylene is in the non-fluorescent form is non-obvious since Saul et al., requires a polydiacetylene film that is in the fluorescent form to be suitable for the technique suggested therein. Accordingly, use of a non-fluorescent form would not be suitable for the express purposes of Saul et al.

Discussion of Case Law

The mere fact that cited art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the cited art suggest the desirability of the modification. No such suggestion appears in the cited art in this matter. The Examiner's attention in kindly directed to *In re Lee* 61 USPQ 2d 1430 (Fed. Cir. 2002) *In re Dembiczak et al.* 50 USPQ2d. 1614 (Fed. Cir. 1999), *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984), *In re Laskowski*, 10 USPQ2d. 1397 (Fed. Cir. 1989) and *In re Fritch*, 23, USPQ2d. 1780 (Fed. Cir. 1992).

In Dembiczak et al, supra, the Court at 1617 stated: "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc., v. M3 Sys., Inc., 157 F.3d. 1340, 1352, 48

USPQ2d. 1225, 1232 (Fed. Cir. 1998) (describing 'teaching or suggestion motivation [to combine]' as in 'essential evidentiary component of an obviousness holding'), In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d. 1453, 1459 (Fed. Cir. 1998) ('the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them');..."

Also, the cited art lacks the necessary direction or incentive to those or ordinary skill in the art to render under 35 USC 103 sustainable. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention needed to sustain a rejection under 35 USC 103. See *Diversitech Corp. v. Century Steps, Inc.* 7 USPQ2d 1315 (Fed. Cir. 1988), *In re Mercier*, 185 USPQ 774 (CCPA 1975) and *In re Naylor*, 152 USPQ 106 (CCPA 1966).

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d. 1923 (Fed. Cir. 1990), *In re Antonie*, 195, USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

No property can be ignored in determining patentability and comparing the claimed invention to the cited art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

Application N .: 09/811,538

Docket No.: 22001-00005-US

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 22001-00005-US from which the undersigned is authorized to draw.

Dated: 7-28-03

Respectfully submitted,

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Contents

CHAPTER 16

Polymer Liquid Crystals

16.1 Introduction

The liquid crystalline state was first observed by an Austrian botanist, Friedrich Reintzer, in 1888, when he noted that cholesteryl esters formed opaque liquids on melting which, on heating to higher temperatures, subsequently cleared to form isotropic liquids. This behaviour was interpreted by Lehmann as evidence for the existence of a new phase lying between the solid and isotropic liquid states. After further work by Friedel this new state became known as a mesophase, from the Greek *mesos* meaning in-between or intermediate. These mesophases are quite fluid but also show birefringence and as they appear to have properties associated with both crystals and liquids, they were called *liquid crystals* by Lehmann.

Liquid crystals can be divided into two main classes; those, like the cholesteryl derivatives, whose liquid crystalline phases are formed when the pure compound is heated are called *thermotropic*, and those where the liquid crystalline phase forms when the molecules are mixed with a solvent are referred to as *lyotropic*. The thermotropic class also includes enantiotropic types where the liquid crystalline phases can be seen on both the heating and the cooling cycles, and monotropic types where the mesophase is stable only on supercooling from the isotropic melt.

Continued investigations led to the identification of three main types of mesophase; a *smectic* state (Greek: *smegma*, meaning soap), a *nematic* state (Greek: *nema* meaning thread) and a *cholesteric* state observed in systems containing molecules with a chiral centre.

While the early work and much of the recent studies have identified and investigated the liquid crystalline properties of many small molecules, it was suggested that polymeric forms could also exist. In 1956, Flory postulated that concentrated solutions of rigid rod-like polymers should form ordered structures in solution at some critical concentration. This phenomenon was observed initially in 1937 for solutions of tobacco mosaic virus, but the first systematic experimental verification of this prediction came from work on concentrated solutions of poly(γ-methyl glutamate) and poly(γ-benzyl glutamate), where these polymers exist in extended helical forms that can pack readily into ordered bundles with the long axes generally aligned in one direction. This produces a quasi-parallel distribution of chains in their solutions and anisotropic liquid crystalline properties. Later it was shown that anisotropic solutions are formed by some aromatic polyamides and cellulose derivatives, where again the molecules are relatively rigid. These are lyotropic systems, but in the 1970s thermotropic liquid crystalline polymers were also synthesized and this latter group has been developed rapidly since then.

16.2 Liquid crystalline phases

Molecules which have a tendency to form liquid crystalline phases usually have either rigid, long lathe-like shapes with a high length to breadth (aspect) ratio, or disc shaped molecular structures. Chemically these may be composed of a central core comprising aromatic or cycloaliphatic units joined by rigid links, and having either polar, or flexible alkyl and alkoxy terminal groups. Some typical examples of possible small molecule structures that from liquid crystalline phases are shown in table 16.1 and these units are called mesogens. When polymers exhibiting liquid crystalline properties are formed they can be constructed from these mesogens in three different ways: (i) incorporation into chain-like structures by linking them together through both terminal units to form main-chain liquid crystalline polymers; (ii) attachment through one terminal unit to a polymer backbone to produce a side chain comb-branch structure; (iii) a combination of both main and side chain structures. The various possible geometric arrangements are shown schematically in figure 16.1

The mesogenic units can then form the ordered structures that are observed in the small molecule systems (though not necessarily the same type of liquid crystalline phase) and are characterized by long-range orientational order, with the long axes of the mesogenic groups arranged in one preferred direction of alignment, called the *director*. When this spatial ordering is such that the mesogens are arranged in regular layers with respect to their centres of gravity, they are in one of several possible smectic phases. The lateral forces between the molecules in the smectic phases are stronger than the forces between the layers, and so slippage of one layer over another provides the characteristic fluidity of the system without losing the order within each layer. A number of different smectic phases can be identified in which the ordered packing of the mesogens in the layers differs and the mesogens are either orthogonal to, or tilted with respect to, the layer structure. These are identified alphabetically. The most ordered is smectic B (S_B) with a hexagonally, close-packed structure for the mesogens in the layers. The S_B and smectic E (S_E) phases exhibit three-dimensional order and have tilted modifications smectic H (S_H) and smectic G (S_G). A much less ordered structure within the layers produces a phase called the smectic A (S_A) phase, where there is a random lateral distribution of the mesogens in the layers. The tilted modification of this is called smectic C (S_C) phase, and both S_A and S_C behave like true two-dimensional liquids. Intermediate in order are the smectic F (S_F) and smectic I (S_I), but the most commonly observed phases are S_A, S_B and S_C.

The nematic phase is much less ordered than the smectic phases. While the lateral ordering of the mesogen long axes is maintained, the centres of gravity are no longer confined in layers, but are distributed randomly in the phase. The nematic phase is much more fluid than the smectic phases but still exhibits birefringence.

A third important category is a variation of the nematic phase and is called the cholesteric state. It is observed when mesogens that enter a nematic phase also have a centre. This imparts a twist to each successive layer in the phase where the direction of the director changes regularly from layer to layer, forming a helical arrangement of the directors in three dimensional space. The chiral nematic state was first observed when cholesteryl derivatives were studied, but has now been detected in

TABLE 16.1. A selection of small molecule mesogens and the associated liquid crystalline behaviour

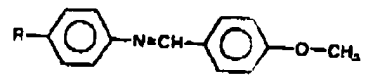
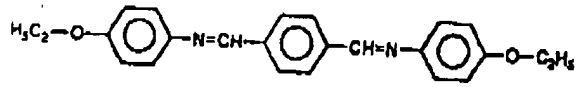
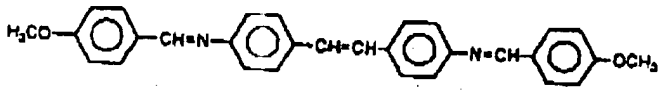
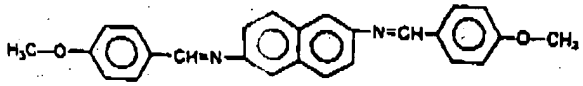
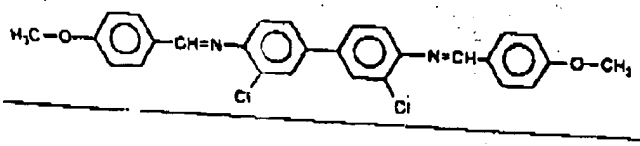
Mesogen	Transition temperature (°C)
 R = —CN, —n-C_4H_9, —O—C_2H_5, —C(=O)—O—CH_3	k 106 n 117 i k 20 n 48 i k 83 n 107 i k 79 n 102 i
	k 200 n 320 i
	k 274 n 340 i
	k 189 n 356 i
	k 154 n 344 (dec) i

TABLE 16.1. A selection of small molecule mesogens and the associated liquid crystalline behaviour (continued)

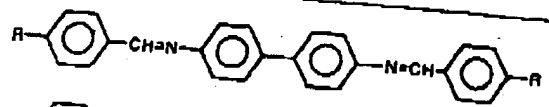
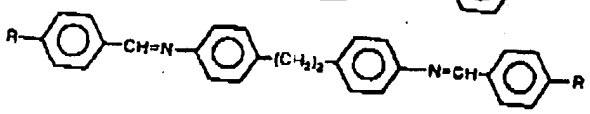
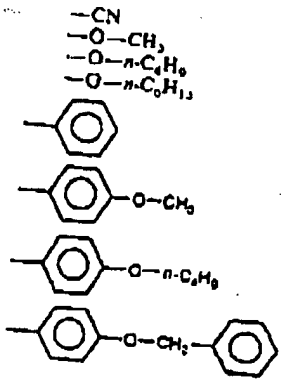
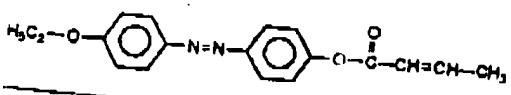
Mesogen	Transition temperature (°C)
 R = —H, —O—CH_3	k 239 n 265 i k 266 n 390 i
 R = —CH_3, —Cl	k 197 n 287 i k 232 n 318 i
 —CN, —O—CH_3, —O—n-C_4H_9, —O—n-C_6H_{13}	k 227 n 367 i k 181 n 337 i k 159 s 186 n 303 i k 127 s 229 n 276 i
	k 227 n 403 i
	k 253 n 270 (dec) i
	k 232 n 331 i
	k 270 n 346 i
	k 110 n 197 i

TABLE 16.1. A selection of small molecule mesogens and the associated liquid crystalline behaviour (*continued*)

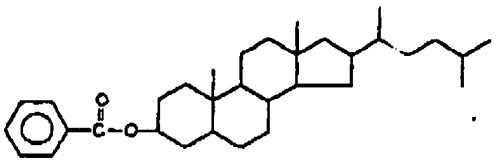
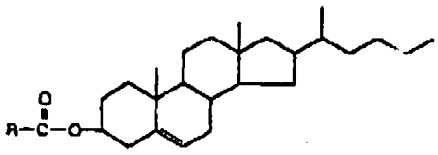
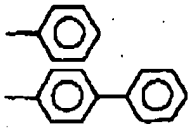
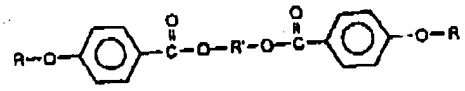
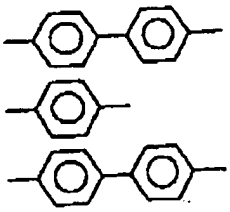
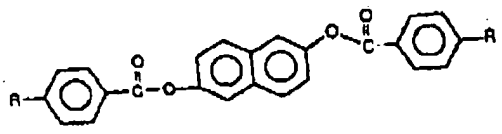
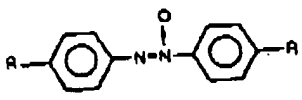
Mesogen		*Transition temperature (°C)*
		k 137 n* 155 i
	R = —Cl	k 118 n* 125 i
	—CH_3	k 55 n* 117 i
	—C_2H_5	k 97 n* 114 i
	—n-C_6H_{13}	k 96 n* 112 i
	—n-C_7H_{15}	k 97 n* 110 i
	—n-C_9H_{17}	k 78 s* 81 n* 92 i
	—$CH(C_2H_5)(CH_2)_3CH_3$	k 30 n* 50 i
	—n-$C_{13}H_{27}$	k 71 s* 79 n* 83 i
	—n-$C_{14}H_{29}$	k 77 s* 79 n* 83 i
	—n-$C_{16}H_{33}$	k 76 s* 80 n* 83 i
	—$(CH_2)_7(CH{=}CH{-}CH_2)(CH_2)_6CH_3$	k 39 s* 44 n* 49 i
	—$(CH_2)_7(CH{=}CH{-}CH_2)_2(CH_2)_3CH_3$	k 20 s* 44 n* 49 i
	—$(CH_2)_7(CH{=}CH{-}CH_2)_3CH_3$	k 35 s* 45 n* 48 i
	—O—$(CH_2)_8(CH{=}CH{-}CH_2)(CH_2)_6CH_3$	k-10 s* 18 n* 31 i
	—O—$(CH_2)_2$—O—$(CH_2)_4$—O—C_2H_5	k-2 n* 15 i
		k 150 n* 178 i
		k 178 s* 290 i

TABLE 16.1. A selection of small molecule mesogens and the associated liquid crystalline behaviour (*continued*)

Mesogen			*Transition temperature (°C)*
	R = —n-C_4H_9	R' = 	k 171 s 184 n 358 (dec) i
	—n-C_5H_{11}		k 33 s 125 n 206 i
			k 150 s 211 n 316 i
	R = —CH_3		k 207 n 318 i
	—O—CH_3		k 220 n 350 i
	—O—n-C_5H_{11}		k 145 n 272 i
	—O—n-C_7H_{15}		k 153 n 245 i
	—O—n-C_9H_{19}		k 144 n 227 i
	R = —O—CH_3		k 119 n 135 i
	—O—C_2H_5		k 139 n 169 i
	—O—n-C_6H_9		k 105 n 136 i
	—O—n-C_8H_{13}		k 81 n 128 i
	—C(=O)—O—C_2H_5		k 114 n 120 i

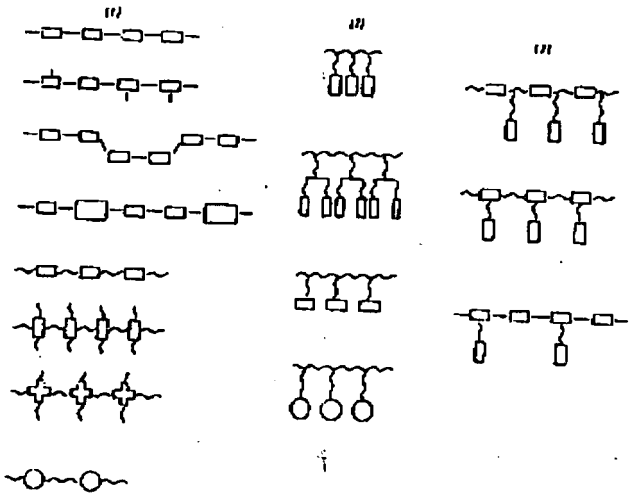


FIGURE 16.1. Schematic representation of various possible arrangements of mesogens in polymer chain structures (1) main chain, (2) side chain, and (3) combinations of main and side chain. (Adapted from D. Sek (1988) with permission from Akademie-Verlag).

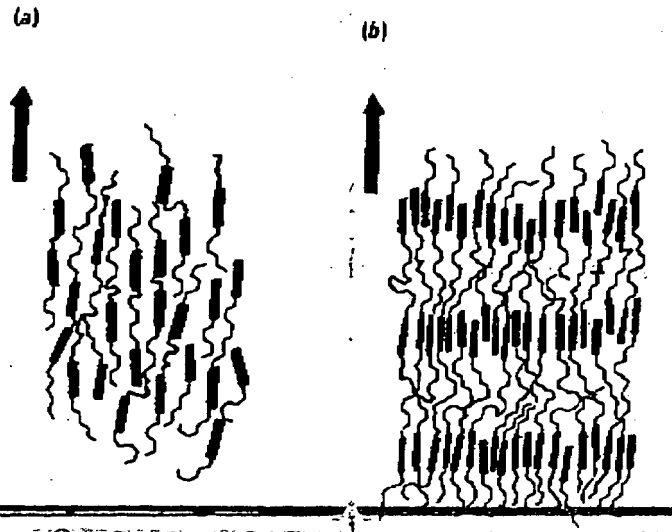
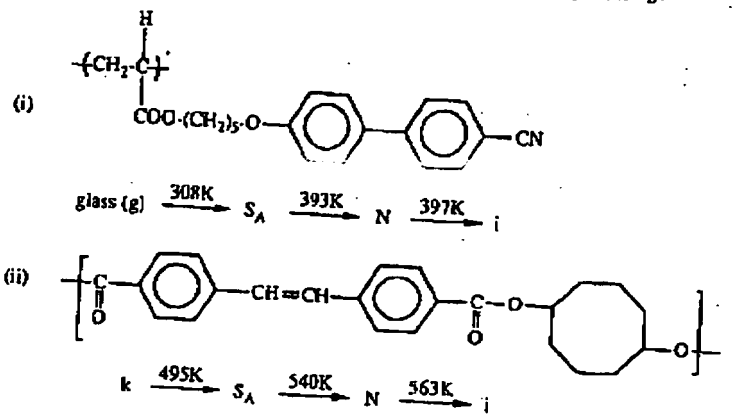


FIGURE 16.2. Schematic diagram of (a) the nematic phase and (b) the smectic phase for main chain liquid crystalline polymers, showing the director as the arrow. The relative ordering is the same for side chain polymer liquid crystals.

other chiral mesogens, and can also be induced by adding small chiral molecules to a host nematic liquid crystalline polymer. The main phase types are shown schematically in figure 16.2

In some polymer liquid crystals, several mesophases can be identified. In main chain liquid crystal polymers there is usually a transition from the crystal to a mesophase, whereas in more amorphous systems when a glass transition is present, the mesophase may appear after this transition has occurred. In multiple transition thermotropic systems, the increase in temperature leads to changes from the most ordered to the least ordered states, *i.e.* crystal(k)→smectic(S)→nematic(N)→isotropic (i), *e.g.*



16.3 Identification of the mesophases

The liquid crystalline phases in polymeric materials are sometimes difficult to identify unequivocally, but several techniques can be used that provide information on the nature of the molecular organization within the phase. If used in a complementary fashion these can provide reliable information on the state of order of the mesogenic groups.

POLARIZING MICROSCOPE

The phases can often be identified by observing the characteristic textures developed in thin layers of the polymer when viewed through a microscope using a linearly polarized light source.

The preparation of the glass slides for sample observation can be important and a homogeneous (or planar) texture, where the mesogens all lie parallel to the surface, can only be obtained if the slide is rubbed in one direction with cotton or similar material. This gives a uniform birefringence, unlike the effects obtained from untreated surfaces where the long axes of the mesogens are all oriented at right angles to the glass and homeotropic alignment results, giving a uniformly dark field; touching the slip can then cause scintillation by tilting the mesogens under the applied pressure. These homeotropic textures can also be prepared by treating the slide with concentrated nitric acid followed by a water and acetone rinse.